

CLAIMS

1. A pharmaceutical composition comprising a solid intimate mixture of human growth releasing factor (GRF) and a stabilizing amount of saccharose, alone or in combination with other excipients.
2. The pharmaceutical composition according to Claim 1, wherein the solid intimate mixture is a lyophilizate.
- 10 3. The pharmaceutical composition according to any of Claims 1 to 2, wherein the stabilizing agent is saccharose alone.
- 15 4. The pharmaceutical composition according to any of claims 1 to 3, containing 3 or 10 mg/vial of hGRF.
- 15 5. The pharmaceutical composition according to any of Claims 1 to 4 comprising 3 or 10 mg/vial of hGRF and 20.52 or 68.4 mg/vial of saccharose.
- 20 6. The pharmaceutical composition according to any of Claims 1 to 5 further comprising buffering agents.
- 25 7. A process for preparing a pharmaceutical composition according to any of Claims 1 to 6, comprising the preparation of an aqueous solution of the components, the distribution within containers and the lyophilization in the containers.
- 30 8. Forms of presentation of said pharmaceutical composition comprising the solid mixture according to any of Claims 1 to 6, hermetically closed in a sterile condition within a container suited for storage before use and for reconstitution of the mixture into a solvent or into a solution for injectables.
9. A solution comprising the solid mixture according to any of Claims 1 to 6, reconstituted in a solvent or a solution for injectables.

10. The solution according to any of Claim 9, wherein the pH is comprised between 4 and 6.